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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/042,766

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Roger deLusignan

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07/19/2006

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EXAMINER

KOPPIKAR, VIVEK D

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/042,766	Applicant(s) DELUSIGNAN ET AL.	
	Examiner Vivek D. Koppikar	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Claims 1-13 have been examined in this application. This Final Office Action is in response to "Amendment" and "Remarks" filed on May 25, 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,322,504 to Kirshner in view of US Patent Application Publication 2002/0072933 to Vonk.

(A) As per claim 1, a method for providing patient-specific best medical practices recommendations for a population of patients suspected of having individual members with a risk for at least one pre-selected medical condition using a central system adapted to customize the recommendations for the individual members (Kirshner: Abstract), wherein said method comprises the steps of:

a) selecting a population of patients that is suspected of having a higher than normal risk for the pre-selected medical condition (Kirshner: Col. 6, Ln. 22-28);

b) collecting personal patient information about the individual members that comprises factors that indicate risk of having or developing the pre-selected medical condition (Kirshner: Col. 6, Ln. 6-19);

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c) processing the personal patient information by the central system to provide a patient analysis outcome that reflects risk assessment of the pre-selected medical condition (Kirshner: Col. 6, Ln. 67-Col. 7, Ln. 7);

d) collecting patient management information about the individual members that comprises a medical history relevant to the pre-selected medical condition (Kirshner: Col. 8, Ln. 49-51);
and

e) processing the patient management information by the central system to provide a recommendations outcome (Kirshner: Col. 17, Ln. 21-39). Kirshner does not teach that the recommendations outcome reflects the best medical practices for future management of the individual members relative to the medical condition, however, this feature is well known in the health care industry as illustrated by Vonk (Section [004]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the method of Kirshner with the aforementioned feature from Vonk with the motivation of providing a patient with advice that is in accordance with the best medical practices in the health care industry, as recited in Vonk (Section [0004]).

(B) As per claim 2, in the combined method of Kirshner in view of Vonk steps d) and e) are repeated at least once (Kirshner: Col. 5, Ln. 47-54). (Users log in multiple times and use the system, therefore, the steps of collecting patient information and providing recommendations occur multiple times or are repeated in the combined system of Kirshner in view of Vonk.)

(C) As per claim 3, in the combined method of Kirshner in view of Vonk the pre-selected medical condition is coronary artery disease (Kirshner: Col. 1, Ln. 17-21).

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(D) As per claims 4-6, the combined method of Kirshner in view of Vonk does not teach that the pre-selected medical condition is diabetes, pulmonary disease or congestive heart failure, however, Kirshner teaches that its system can be used to determine the risk of developing diseases (Kirshner: Col. 1, Ln. 7-14). The examiner takes the position that diabetes, pulmonary disease and congestive heart failure are encompassed by, and within the scope of the term "disease" as used in Kirshner.

(E) As per claim 7, in the combined method of Kirshner in view of Vonk the recommendations outcome is sent to a healthcare provider via mail, e-mail, or is accessible by a healthcare provider over an internet web page (Kirshner: Col. 2, Ln. 16-30).

(F) As per claim 8, in the combined method of Kirshner in view of Vonk the central system is pre-programmed with algorithms that allow for customization of output based on professional associations' evidence-based best practices according to the individual member's patient management information (Kirshner: Col. 15, Ln. 64-Col. 16, Ln. 3).

(G) As per claim 9, in the combined method of Kirshner in view of Vonk the personal patient information is collected using a risk assessment survey that is completed by the individual member (Kirshner: Col. 6, Ln. 6-19).

(H) As per claim 10, in the combined method of Kirshner in view of Vonk the patient management information is collected using data collection tool that is completed by a healthcare provider (Kirshner: Col. 5, Ln. 42-45).

(I) As per claim 11, Kirshner teaches a system for providing patient-specific best medical practices recommendations for a population of patients suspected of having individual members with the risk for at least one pre-selected medical condition comprising a central system adapted

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to customize the recommendations for the individual members (Kirshner: Abstract), or and said system comprises:

- a) a CPU programmed to receive and analyze personal patient information that comprises factors that indicate risk of having or developing the pre-selected medical condition (Kirshner: Col. 2, Ln. 16-30);
- b) a first output device adapted to provide patient analysis outcome that reflects risk assessment of the pre-selected medical condition (Kirshner: Col. 2, Ln. 16-30);
- c) a CPU programmed to receive and analyze patient management information about the individual members that comprises a medical history relevant to the pre-selected medical condition (Kirshner: Col. 2, Ln. 16-30); and
- d) a second output device, wherein said second output device is the same or different than the first output device, adapted to provide recommendations outcome (Kirshner: Col. 17, Ln. 21-39) that reflects best medical practices for future management of the individual members relative to the medical condition. Kirshner does not teach that the recommendations outcome reflects the best medical practices for future management of the individual members relative to the medical condition, however, this feature is well known in the health care industry as illustrated by Vonk (Section [004]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Kirshner with the aforementioned feature from Vonk with the motivation of providing a patient with advice that is in accordance with the best medical practices in the health care industry, as recited in Vonk (Section [0004]).

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(J) As per claim 12, the combined system of Kirshner in view of Vonk further comprises at least one central server that is accessible on line and at least one remote access terminal (Kirshner: Col. 2, Ln. 16-30).

(K) As per claim 13, in the combined system of Kirshner in view of Vonk the output device of (b), (d) or both (b) and (d) further comprises a communications interface capable of transmitting output on-line (Kirshner: Col. 2, Ln. 16-30).

Response to Arguments

4. Applicant's arguments filed on May 25, 2006 have been fully considered but they are not persuasive. The applicants arguments will be addressed and responded to in sequential order as they were presented in the "Remarks" section filed on the above mentioned date.

(1) Applicants argue that the Kirshner reference does not explicitly disclose the step of selecting a population of patients. The applicants also go on to argue that the Vonk reference also does not teach the selection step.

To respond to this argument, the examiner would like to point out that the Kirshner reference does in fact teach this very feature (Col. 5, Ln. 60-Col. 6, Ln. 28). The examiner, furthermore takes the position that the selection step of the instant invention refers to the system proceeding in or engaging in some sort of action with regards to a patient if the patient meets certain pre-determined or pre-established criteria. In the current invention this step encompasses providing these selected patients with best medical practices recommendations. Similarly, in Kirshner, if the system determines (suspects) that a patient has had a pre-existing health condition or disease the system "selects" these patients to receive a query asking the patient if

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they want to learn about risk factor modification (which is similar to the best medical practices recommendations in the instant invention) (Kirshner: Col. 6, Ln. 10-20).

(2) The applicants next argue that, with regard to claims 5 and 6, there is no explicit disclosure in either reference of pulmonary disease or congestive heart failure as the pre-selected medical condition.

To respond to this argument, the examiner would like to point out that Kirshner teaches that its computerized interactive method can be used to assess the risk for any disease and coronary artery disease is simply an exemplary example (Kirshner: Col. 1, Ln. 5-15). Furthermore, the applicants have not pointed to any evidence, teaching or suggestion to show that the teachings of Kirshner cannot be used to provide recommendations to patients for pulmonary disease, or congestive heart failure.

(3) The applicants next argue that, with regard to claim 7, Kirshner merely discloses that an individual may use the Internet to access the system, but does not disclose that the recommendations outcome is sent to a health care providers. Applicants further argue that Vonk discloses Internet communications but does not disclose the step of sending recommendations outcomes to a health care provider.

To respond to this argument, the examiner would like to point out that the Kirshner teaches a computerized interactive method and system for determining a risk of developing a disease and the consequences of developing a diseases and the entire method taught by Kirshner is carried out over the Internet (Kirshner: Col. 2, Ln. 15-36). The examiner takes the position that it is within the scope of Kirshner that the user can be a health care provider who is using the system and entering data into the system on behalf of a patient. Furthermore, Kirshner sends the

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recommendations outcome to the user (Kirshner: Col. 2, Ln. 49-55). Kirshner does not mention any other means of communicating to the user other than via the Internet (i.e. webpage or e-mail) and therefore the examiner takes the position that the recommendations outcome (Kirshner: Col. 2, Ln. 49-55) taught in Kirshner is sent to the user (e.g. health care provider) either via e-mail or is accessible to the user over an Internet web page.

(4) The applicants argue that the examiner has failed to provide the requisite motivation to combine or modify the cited reference to achieve the claimed invention. However, the examiner has set forth the motivation, above, in the rejection of claim 1 and this motivation is taken directly from Vonk (Section [0004]). Therefore, this argument advanced by the applicants has no merit.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

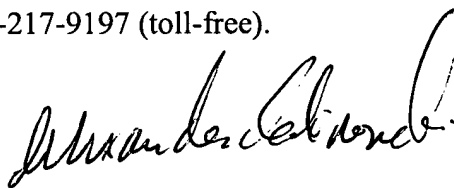
If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,


Vivek Koppikar

7/7/2006



ALEXANDER KALINOWSKI
SUPERVISORY PATENT EXAMINER